Tecentriq® (atezolizumab) – Expanded indication

- On June 19, 2018, the FDA approved Genentech's Tecentriq (atezolizumab), for the treatment of patients with locally advanced or metastatic urothelial carcinoma who: are not eligible for cisplatin-containing chemotherapy, and whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 5% of the tumor area), or are not eligible for any platinum-containing chemotherapy regardless of level of tumor PD-L1 expression.
    - Previously, Tecentriq was approved for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy.
    - Tecentriq is also approved for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy.
    - This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- Tecentriq is also indicated for the treatment of metastatic non-small cell lung cancer.
- The expanded indication for Tecentriq was demonstrated in the IMvigor210 (Cohort 1) study of 119 patients with locally advanced or metastatic urothelial carcinoma who were ineligible for cisplatin-containing chemotherapy and were either previously untreated or had disease progression at least 12 months after neoadjuvant or adjuvant chemotherapy. A total of 32 patients had tumors expressing PD-L1 of ≥ 5%. Major efficacy outcomes included overall response rate (ORR) and duration of response (DoR).
    - The ORR was 28.1% (95% CI: 13.8, 46.8) in the 32 patients with tumors expressing PD-L1 of ≥ 5%.
    - The DoR was not reached in this group of 32 patients (range in months: 8.1, 15.6+).
- The recommended dosage of Tecentriq for all indications is 1,200 mg as an intravenous infusion over 60 minutes every 3 weeks until disease progression or unacceptable toxicity.